

are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**Direct Comments to OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Scudder Quandra, Project Officer, NIH/NIDA/CCTN, Room 3105, MSC 9557, 6001 Executive Boulevard, Bethesda, MD 20892-9557 or e-mail your request, including your address to [scudderq@nida.nih.gov](mailto:scudderq@nida.nih.gov).

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: April 15, 2010.

Mary Affeldt,  
Executive Officer, (OM Director, NIDA),  
National Institutes of Health.

[FR Doc. 2010-9374 Filed 4-22-10; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2009-E-0172 and FDA-2009-E-0174]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; VIMPAT —NDA 22-253

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for VIMPAT based on new drug application (NDA) 22-253 for VIMPAT TABLETS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extensions of patents which claim the human drug product, VIMPAT. The regulatory review period determination for VIMPAT Injection is publishing in this issue of the *Federal Register*.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product, VIMPAT (lacosamide). VIMPAT tablets are indicated as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for VIMPAT (U.S. Patent Nos. 5,654,301 and RE38,551) from Research Corporation Technologies, Inc., and the Patent and Trademark Office requested

FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 29, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VIMPAT represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VIMPAT is 3,452 days. Of this time, 3,055 days occurred during the testing phase of the regulatory review period, while 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* May 19, 1999. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 19, 1999.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* September 28, 2007. FDA has verified the applicant's claim that the new drug application (NDA 22-253) for VIMPAT tablets was submitted on September 28, 2007.

3. *The date the application was approved:* October 28, 2008. FDA has verified the applicant's claim that NDA 22-253 was approved on October 28, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,827 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 22, 2010. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 20, 2010. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 22, 2010.

Jane A. Axelrad,  
Associate Director for Policy, Center for Drug  
Evaluation and Research.

[FR Doc. 2010-9512 Filed 4-22-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2009-E-0175 and FDA-  
2009-E-0173]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; VIMPAT—NDA 22-254

AGENCY: Food and Drug Administration,  
HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for VIMPAT based on new drug application (NDA) 22-254 for VIMPAT injection and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim the human drug product, VIMPAT. The regulatory review period determination for VIMPAT Tablets is publishing in this issue of the *Federal Register*.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 0993-0002, 301-796-3602.

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417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product VIMPAT (lacosamide). VIMPAT injection is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older when oral administration is temporarily not feasible. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for VIMPAT (U.S. Patent Nos. 5,654,301 and RE38,551) from Research Corporation Technologies, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 29, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VIMPAT represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VIMPAT is 3,452 days. Of this time,

3,055 days occurred during the testing phase of the regulatory review period, while, 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* May 19, 1999. The applicant claims November 14, 2003, as the date an investigational new drug application (IND) became effective. However, according to FDA records, this IND was not the first IND received for this active ingredient. In general, FDA has used the first IND of the active ingredient of the drug product as the beginning of the testing phase, if information derived from this first IND was or could have been relied on or was relevant for approval to market the drug product. FDA records indicate that the effective date of the first IND for lacosamide was May 19, 1999, which was 30 days after FDA receipt of this first IND. This is the same IND and the same date FDA determined was the beginning of the regulatory review period for Vimpat Tablets approved under new drug application (NDA) 22-253. The regulatory review period determination for VIMPAT Tablets is publishing in this issue of the *Federal Register*.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* September 28, 2007. FDA has verified the applicant's claim that the new drug application (NDA) 22-254 for VIMPAT injection was submitted on September 28, 2007.

3. *The date the application was approved:* October 28, 2008. FDA has verified the applicant's claim that NDA 22-254 was approved on October 28, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,104 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 22, 2010. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 20, 2010. To meet its burden,